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510(K) SUMMARY
OF SAFETY AND EFFECTIVENESS

JAN - 7 2008

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the BIOFOAM™ Bone Wedge.

Submitted By:	Wright Medical Technology, Inc.
Date:	November 19, 2007
Contact Person:	Brian Young Sr. Director, Regulatory Affairs
Proprietary Name:	**BIOFOAM™ Bone Wedge**
Common Name:	Bone Wedge
Classification Name and Reference:	21 CFR 888.3040/ HWC Smooth or threaded metallic bone fixation fastener – Class II 21 CFR 888.3030/ HRS Single/multiple component metallic bone fixation appliances and accessories – Class II
Device Product Code and Panel Code:	Orthopedics/87/HWC & Orthopedics/87/HRS

DEVICE INFORMATION

A. INTENDED USE

The BIOFOAM™ Bone Wedge is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot, such as:

- Opening wedge osteotomies of Hallux Valgus
- Evans lengthening osteotomies
- Metatarsal/cuneiform arthrodesis

The BIOFOAM™ Bone Wedge is not intended for use in the spine.

B. DEVICE DESCRIPTION

The BIOFOAM™ Bone Wedge is a titanium metal foam wedge used for angular correction of small bones in the ankle and foot. It is offered in one distinct design with varying widths and thicknesses to accommodate a variety of small bone applications.

C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features, material, and indications for use of the BIOFOAM™ Bone Wedge are substantially equivalent to the previously 510(k) cleared Small Bone Wedge. The safety and effectiveness of the BIOFOAM™ Bone Wedge is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2008

Wright Medical Technologies, Inc.
% Mr. Brian Young
5677 Airline Road
Arlington, TN 38002

Re: K073535
Trade/Device Name: BIOFOAM Bone Wedge
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.
Regulatory Class: II
Product Code: HRS, HWC
Dated: November 19, 2007
Received: December 17, 2007

Dear Mr. Young:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073535

Device Name: BIOFOAM™ Bone Wedge

Indications For Use:

The BIOFOAM™ Bone Wedge is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot, such as:

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- Metatarsal/cuneiform arthrodesis.

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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FOR M. MELKERSON

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073535